

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

## **ELECTRONIC MAIL**

March 24, 2021

Jolanta Ozatalay Regulatory Affairs Project Manager Fine Agrochemical LTD 12733 Director's Loop Woodbridge, VA 22192

Subject: NAA: AMVAC Request that EPA Review Required Data for 1-Naphthaleneacetic Acid Technical Sodium Salt (EPA Reg. No. 62097-35) and 1-Naphthaleneacetic Acid Technical Potassium Salt (EPA Reg. No. 62097-36) as Part of the Registration Review of NAA

Dear Ms. Ozatalay,

The Environmental Protection Agency (EPA or the Agency) received a request from the AMVAC Chemical Corporation (AMVAC) to review the Generic Data-Call Ins (GDCI) issued for the registration review of 1-Naphthaleneacetic acid, its salts, ester, and acetamide, collectively referred to as naphthalene acetates and hereafter will be referred to as NAA. As you are aware, this case includes the following six active ingredients: napthalene acetamide (PC code 056001), napthalene acetic acid (PC Code 056002), potassium 1-napthalene acetate (napthalene acetic acid, potassium salt; PC Code 056003), ammonium 1-napthalene acetate (napthalene acetic acid, ammonium salt, PC Code 056004), sodium 1-napthalene acetate (napthalene acetic acid, sodium salt, PC Code 056007), and ethyl 1-napthalene acetate (napthalene acetic acid, ethyl ester, PC Code 056008). In the request, AMVAC asserts that in the registration review of NAA, a study generated with a test substance of one active ingredient supports the other active ingredients in the case.

The Agency has reviewed the request and determined that the studies outlined below in Tables 1 and 2 were necessary for the registration review of all the active ingredients included in the NAA registration review case. Therefore, these studies are required for all the technical products included in this case.

It is our understanding that Fine Agrochemical, LTD (Fine) holds technical registrations for 1-napthaleneacetic acid technical sodium salt and 1-napthaleneacetic acid technical potassium salt and therefore will be subject to the requirements listed in Tables 1 and 2. The Agency plans to issue a GDCI later this year to Fine for the additional studies deemed necessary for the registration review of NAA as listed below.

Table 1

Guideline Number	Study Title	Original GDCI Number and PC Code
	Table 1.1 Aquatic Toxicity Dat	a
850.1400	Freshwater fish early-life	GDCI-056001-1520 (NAD)
<u> </u>	stage (chronic)	
850.1075	Saltwater fish acute toxicity	GDCI-056001-1520 (NAD)
850.1010	Aquatic Invertebrate Acute	GDCI-056001-1520 (NAD)
	(Freshwater)	
850.1300	Freshwater Invertebrate Life	GDCI-056001-1520 (NAD)
	Cycle (Chronic)	
850.1035	Saltwater Invertebrate Life	GDCI-056001-1520 (NAD)
	Cycle (Chronic)/Mysid Acute	
	(Marine/Estuarine)	
850.4550	Cyanobacteria Toxicity	GDCI-056002-1521(NAA)
850.4500	Algal Toxicity (Freshwater –	GDCI-056002-1521(NAA)
	Navic)	
850.4500	Algal Toxicity (Marine –	GDCI-056002-1521(NAA)
	Skeletonema)	
	Table 1.2 Terrestrial Toxicity Da	ata
SS-1311	Honey Bee Adult Acute Oral	GDCI-056002-1521(NAA)
SS-1313	Honey Bee Adult Chronic	GDCI-056002-1521(NAA)
	Oral	
SS-1314	Honey Bee Larvae Chronic	GDCI-056002-1521(NAA)
	Oral	
	<b>Table 1.3 Residue Data</b>	
850.6100	Environmental Chemistry	GDCI-056002-1521(NAA)
	Methods and Validations	
860.1340	Validation of CPS Residue	GDCI-056002-1521(NAA)
	Method	, ,
860.1520	Citrus Processing Study	GDCI-056002-1521(NAA)
860.1380 [also included	Storage Stability Study for	GDCI-056002-1521(NAA)
860.1000]	Citrus Residues	
	Table 1.4 Environmental Fate Da	ata
835.1230	Absorption/Desorption	GDCI-056002-1521(NAA)
835.4100	Aerobic Soil Metabolism	GDCI-056002-1521(NAA)

Additionally, the toxicology data outlined in Table 2 below were also used in the risk assessments and are necessary to support registration. Although these studies were not included in the GDCI for registration review, they were submitted by AMVAC in 2005 and were used to support registration review.

Table 2

Guideline Number	Study Title	PC Code	
Table 2.1 Additional Toxicology Data			
870.3700	Prenatal Development	NAA, Na Salt (PC Code:	
	Toxicity Study in Rabbit	056007)	
870.3700	Prenatal Development	NAA, Na Salt (PC Code:	
	Toxicity Study in Rats	056007)	
870.4200	80 Week Carcinogenicity	NAA, Na Salt (PC Code:	
	Study in Mice	056007)	

Please feel free to contact Anna Romanovsky of my staff if you have any questions. She may be reached by phone at (703) 347-0203 or by email at romanovsky.anna@epa.gov.

Sincerely,

Kelly W. Sherman Kelly Sherman

Chief

Risk Management and Implementation Branch 3

Pesticide Re-evaluation Division